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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,192	08/09/2001	Dan W. Denney JR.	GENITOPE-06493	5113

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EXAMINER	
YAEN, CHRISTOPHER H	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 02/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/925,192	DENNEY, DAN W.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RE: Denney D
Priority Date: 1 May 1996

Election/Restrictions

1. Applicant's election without traverse of group III (claims 35-39) in the reply filed on 11/8/2004 is acknowledged.

2. Accordingly, claims 25-34 are canceled without prejudice or disclaimer.

3. Claims 35-39 are pending and examined on the merits.

Information Disclosure Statement

4. The Information Disclosure Statement filed and 1/26/04 is acknowledged and considered. A signed copy of the IDS is attached hereto. The IDS filed 11/8/2004 appears to be a duplicate of the IDS filed 1/26/2004.

Claim Rejections - 35 USC § 112, 1st paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION. In

claim 35 and dependent claims thereof, step "d)" recites the ratio of 2:20-2:50 of amplification vector to first or second expression vector. The specification on page 26 specifically states that if a vector encoding a selectable marker is not employed then the ratio of amplification vector to expression vector is in the range of 1:10-15::amplification vector:expression vector. Even if a vector encoding a selectable marker is used the ratio is 2:20-25::amplification vector:expression vector. Therefore the ratio of 2:50 is outside of the range disclosed and does not find support in the specification as originally filed. Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 35-39 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

The current claims are drawn to a method of producing a vaccine for the treatment of B-cell lymphoma comprising the steps of

a) providing: (i) malignant cells isolated from a patient having a B-cell lymphoma; (ii) an amplification vector comprising a recombinant oligonucleotide having a sequence encoding a first inhibitable enzyme operably linked to a heterologous promoter; (iii) a T lymphoid parent cell line;

b) isolating from said malignant cells nucleotide sequences encoding at least one V_H region and at least one V_L region, said V_H and V_L regions derived from immunoglobulin molecules expressed by said malignant cells;

c) inserting said nucleotide sequence encoding said V_H region into a first expression vector, and inserting said nucleotide sequence encoding said V_L region into a second expression vector;

d) introducing said first and second expression vectors and said amplification vector into said parent cell to generate transformed cells, wherein a ratio ranging from 2:20 to 2:50 of said nmplification vector to said first or second expression vector is employed;

e) introducing said transformed cells into a first aqueous solution, said first aqueous solution comprising an inhibitor capable of inhibiting said first inhibitable enzyme, wherein the concentration of said inhibitor present in said first aqueous solution is sufficient to prevent growth of said parent cell line; and identifying a transformed cell capable of growth in said first aqueous solution, wherein said transformed cell capable of growth expresses said V_H and V_L regions.

Credible Utility

Following the requirements of the Utility Guidelines (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.), the first inquiry is whether a credible utility is cited in the specification for use of the claimed product. In this case, the product is a vaccine for the treatment of B-cell lymphoma.

The specification cites, that to overcome the problems of somatic variation associated with Ig molecules isolated from B-cell lymphomas, multivalent vaccines which are capable of representing the full spectrum of Ig variants is required. Thus one of the utilities cited in the instant application is as a multivalent vaccine for active idiotype therapy (see pages 53 and 54, lines 10-21, for example). This utility, however, is not credible.

In the instant case, a vaccine for the treatment of B-cell lymphoma is not a credible utility, because based on the broadest reasonable interpretation, the claimed method produces a vaccine which reads on a product intended for prophylactic treatment of B-cell lymphoma and also on a product which is intended to be used on members of the population whom are pre-disposed to acquiring this specific disease. The determination of pre-disposition is essentially equivalent to a crystal ball into the future.

The art teaches that in general, the treatment of cancer is at most unpredictable as underscored by Gura (Science, v278, 1997, pp.1041-1042) who discusses the potential shortcomings of potential anti-cancer agents including extrapolating from in-vitro to in-vivo protocols, the problems of drug testing in knockout mice, and problems associated with clonogenic assays. Indeed, since formal screening began in 1955, thousands of drugs have shown activity in either cell or animal models, but only 39 that are used exclusively for chemotherapy, as opposed to supportive care, have won approval from the FDA (page 1041, 1st column) wherein the fundamental problem in drug discovery for cancer is that the model systems are not predictive. Moreover,

reasonable guidance with respect to preventing any cancer (not just lymphomas) relies on quantitative analysis from defined populations which have been successfully pre-screened and are predisposed to particular types of cancer. This type of data might be derived from widespread genetic analysis, cancer clusters, or family histories. The essential element towards the validation of a preventive therapeutic is the ability to test the drug on subjects monitored in advance of clinical cancer and *link* those results with subsequent histological confirmation of the presence or absence of disease. This irrefutable link between antecedent drug and subsequent knowledge of the prevention of the disease is the essence of a valid preventive agent. Further, a preventive administration also must assume that the therapeutic will be safe and tolerable for anyone susceptible to the disease. While various antibody-based therapeutics have shown some promising efficacy in the therapy of cancer, (Weiner L.M., Seminars Oncology, Vol. 26, No. 4, Suppl 12, pages 41-50, 1999), a recent review of such therapies did not indicate nor suggest that such therapies would be successful in the prevention of cancer. Furthermore, Weiner teaches (page 43) that one of the obstacles to successful monoclonal antibody therapy is insufficient target specificity. Thus, for an antibody to be somewhat successful there must be a target.

Thus given the contemporary knowledge in the art, the treatment of B-cell lymphomas using antibody immunotherapy is at best unpredictable and therefore vaccines, which are intended as preventative medicaments, are not viewed as credible utilities.

Therefore since a vaccine with the intended purpose of preventing a cancer, in this case B-cell lymphoma, has been established as a non-credible utility, a method of producing a vaccine is also lacking a credible utility. The claims are interpreted with its broadest reasonable interpretation, and if the product which is made by a specific method is considered as lacking a utility, then the method by which the product is made also lacks utility.

Claims 35-39 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
February 15, 2005

GARY NICKOL
PRIMARY EXAMINER

JASEMINE C. CHAMBERS
DIRECTOR
TECHNOLOGY CENTER 1600